




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460


OFFICE OF CHEMICAL
SAFETY AND
POLLUTION PREVENTION

Wednesday, February 02, 2011

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 10324-ERN
DP Barcode: D384359
Product Name: Maquat 4450-CTM

From: Ian Blackwell, Biologist 
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Through: Karen Hicks, Team Leader
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To: Velma Noble, PM 31/ *Tracy Lantz*
Regulatory Management Branch
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Applicant: Mason Chemical Company

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Didecyl dimethyl ammonium chloride	50.0
<u>Other Ingredient(s):</u>	<u>50.0</u>
Total:	100.00

- I BACKGROUND: The Mason Chemical Company asks for the waiver of each of the acute toxicity studies for their new product, "Maquat 4450-CTM". The basis of the waiver is that the product contains **37% methanol** (also known as methyl alcohol or wood alcohol), CAS No. 67-56-1. Methanol is widely known to be very toxic; one citation (<http://www.antizol.com/mpoisono.htm>) describes it as "a highly toxic alcohol". It is probably the only *single* chemical (as opposed to a group of chemicals, like petroleum distillates) that can be used as an inert ingredient in EPA-registered pesticide formulations that must be listed on the product label (when present in concentrations of 4% or more).

The EPA's Reregistration Eligibility Decision of Aliphatic Alkyl Quaternaries (DDAC), EPA 739-R-06-008, 8/2006 gives the following acute toxicity profile for Didecyl Dimethyl Ammonium Chloride (DDAC):

Study	MRID Number	Toxicity Category
Acute Oral Toxicity	422961-01, 413944-04	II
Acute Dermal Toxicity	420538-01	III
Acute Inhalation Toxicity	00145074	II
Primary Eye Irritation	421616-02, 413606-01	I
Primary Skin Irritation	413944-04	I
Dermal Sensitization	463676-01	Nonsensitizer

The Chemistry and Toxicology Team (CTT) is unable to locate a *complete* acute toxicity profile for methanol (official or otherwise). Some toxicity information conflicts with other similar studies. However, a Material Safety Data Sheet (MSDS) for methanol by Microbial ID Chemicals states "Methanol is significantly less toxic to most experimental animals than humans, because most animal species metabolize methanol differently. Non-primate species do not ordinarily show symptoms of metabolic acidosis or the visual effects which have been observed in primates and humans."

CTT contacted Mason Chemical Company representative Erin Tesch to discuss the probable toxicity profile of 10324-ERN. Ms. Tesch stated that Mason was willing to accept toxicity category I for each of the five study guidelines (not dermal sensitization).

II RECOMMENDATIONS:

1. CTT will base the acute toxicity profile for EPA File Symbol 10324-ERN upon the toxicity profile of technical methanol in conjunction with the acute

toxicity profile of technical didecyl dimethyl ammonium chloride. As we are citing data, this is not actually considered a data waiver. Nonetheless, *CTT is not requiring the registrant to submit further data in support of this product.*

2. Some sources of data concerning methanol state information that demonstrate methanol would not be classified toxicity category I for the five acute toxicity studies which are assigned a numerical toxicity category (again, this excludes dermal sensitization). However, CTT is reluctant to assign lower toxicity categories for any of these studies. Noting that we have been informed that the registrant is willing to accept toxicity category I across the board, CTT assigns the studies in this manner. As methanol is known to have different levels and types of toxicity in humans than in the regular acute toxicity test animals (rats, rabbits, mice, etc.), CTT does not know how Mason Chemicals would conduct a set of acute toxicity studies for this product.
3. Dermal sensitization studies conducted in the past state that many alcohols (e.g., ethanol) are dermal sensitizers. As such, CTT classifies 10324-ERN as a dermal sensitizer.

The acute toxicity profile for File Symbol 10324-ERN is currently:

Study	MRID Number	Toxicity Category	Study Status
Acute Oral Toxicity	None	I	Cited
Acute Dermal Toxicity	None	I	Cited
Acute Inhalation Toxicity	None	I	Cited
Primary Eye Irritation	None	I	Cited
Primary Skin Irritation	None	I	Cited
Dermal Sensitization	None	Sensitizer	Cited

III LABELING:

1. The Signal Word is "DANGER" based upon the toxicity categories for acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, primary eye irritation, and primary skin irritation. Also, the EPA's Label Review Manual states that for products containing 4% or more methanol, regardless of the toxicity categories noted in the acute toxicity review, the Signal Word must be DANGER.
2. The EPA's Label Review Manual states, the word "POISON" and the skull and crossbones symbol ☠ are required for products containing 4% or more methanol. (This product contain 37% methanol.)

3. The Precautionary Statements must state:

"Poison. Corrosive. Causes irreversible eye damage. Methanol may cause blindness. Causes skin burns. Fatal if swallowed, inhaled or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not inhale vapor or spray mist. Wear goggles, face shield or safety glasses. Wear chemical-resistant (such as nitrile or butyl) gloves, apron and/or clothing. Wear a respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix T C-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge with any N, R, P or HE prefilter. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using restroom. Remove and wash contaminated clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals."

4. The Statements of Practical Treatment must state:

If in Eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a Poison Control Center or doctor for treatment advice.

If on Skin or Clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a Poison Control Center or doctor for treatment advice.

If Inhaled:

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a Poison Control Center or doctor for treatment advice.

If Swallowed:

- Call a Poison Control Center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a Poison Control Center or doctor.
- Do not give anything by mouth to an unconscious person.

"Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage."

"Have product container or label with you when calling a Poison Control Center or doctor for treatment advice."

"For emergency information on [product, use, etc.], call the National Pesticides Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific time (PT), seven days a week. During other times, call the poison control center 1-800-222-1222."

5. This product meets the Agency requirements for Restricted-Use Classification based on data that place it in toxicity category I for acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, primary eye irritation and primary skin irritation. This product contains an inert ingredient which the EPA specifically recognizes as a poison. In lieu of assigning the product Restricted-Use classification, the product manager may consider alternatives such as face shield or goggles (to mitigate the identified hazards). Please refer to the 40 CFR §152.170 for information on Restricted-Use products.
6. Based upon data placing it in toxicity category I for acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, primary eye irritation and primary skin irritation, this product meets the Agency requirements for Child-Resistant Packaging (CRP). However, the Agency does not require products that are assigned Restricted-Use status to be placed in CRP *in addition to* Restricted-Use Classification. Please refer to the 40 CFR, §157.22 and 157.24 for CRP requirements and exemptions. Thus, CTT recommends that this product be assigned Restricted-Use classification; if not, this product should at least be packaged in CRP.
7. Statements for Contaminated Personal Protective Equipment (Label Review Manual, Chapter 10, 6, B):

"Follow the manufacturer's instructions for cleaning/ maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."